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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/618,307	07/18/2000	Clements C. Lambeth	WEYE115226	9512
26389	7590	10/18/2004		
CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC 1420 FIFTH AVENUE SUITE 2800 SEATTLE, WA 98101-2347				
			EXAMINER FOX, DAVID T	
			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/618,307

Applicant(s)

LAMBETH ET AL.

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>29 June 2004</u> . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>23 July 2004</u> . | 6) <input type="checkbox"/> Other: _____. |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's resubmission of references in the Information Disclosure Statement of 23 July 2004 is gratefully acknowledged.

Claims 20-31 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 2-3 of the last Office action.

Claims 20-31 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on page 3 of the last Office action.

Claims 20-31 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bridgwater in view of El-Kassay et al and Stoeher et al (1998), as stated on page 3 of the last Office action.

No claim is allowed.

Applicant's arguments filed 23 July 2004 have been fully considered but they are not persuasive.

Applicant urges that the written description rejection is improper, given the mischaracterization of the claimed invention by the Examiner, the lack of a requirement that the actual DNA sequences of the markers be known, and the impracticality of providing every possible sequence for every possible marker from every possible tree species.

The Examiner maintains that the claimed invention is directed to the identification of "elite trees" via the correlation of a phenotypic score and a pedigree which was determined via DNA markers. The invention is not merely drawn to the use of DNA fingerprinting to distinguish individuals, but is drawn to a measure of phenotype and the ability of the DNA fingerprint to be predictive of the ability of the individual to transmit particular traits to the progeny. Thus, the references and reasoning relied upon by the Examiner are appropriate.

Regarding the alleged lack of a requirement that the markers be sequenced, the Examiner maintains that the claims encompass any type of DNA marker including SSRs and SNPs, both of which do in fact require extensive DNA sequencing. Applicant is directed to Edwards et al, Krauss et al, and Anzidei et al, all submitted with the Information Disclosure Statement of 23 July 2003. See Edwards et al, page 3, bottom paragraph and page 4, bottom two paragraphs, who teach the requirement of sequencing for SNPs. The requirement for DNA sequencing when using SSRs is taught by Krauss et al, page 535, top paragraph; and Anzidei et al, page 6, penultimate paragraph.

Regarding the alleged impracticality of furnishing sufficient sequence information to adequately describe the extremely broadly claimed genus, encompassing a multitude of marker types from a multitude of tree species, the Examiner maintains that such impracticality is not a criterion for exemption from satisfying 35 USC 112, first paragraph, as it pertains to the written description requirement.

Applicant urges that the enablement rejection is improper, given the lack of applicability of the Staub et al and White references relied upon by the Examiner, the mischaracterization of the Lambeth et al reference relied upon by the Examiner, and the resubmission of additional references by Applicant in the Information Disclosure Statement of 23 July 2004.

The Examiner maintains that the claimed invention is indeed directed to the correlation of DNA marker data and particular traits, as stated above. Thus, Staub et al is eminently applicable. Regarding White, the Examiner maintains that the instantly exemplified polymix-mediated method of breeding approximates open pollination rather than single seed descent breeding, so that the teachings by White of the unpredictability inherent in open pollination-mediated breeding are in fact applicable to the instant situation. Regarding Lambeth et al, the Examiner maintains that the reference teaches the need for the development of additional markers and additional polymix systems, neither of which are taught by the instant specification.

See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an]

enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Regarding the additional references supplied by Applicant, the Examiner maintains that these references support the Examiner's position, in their teachings that the isolation and sequencing of a multitude of non-exemplified markers require undue experimentation, that each different molecular marker system encompassed by the broad claims possesses its own particular shortcomings and unpredictable aspects, and that certain tree species are more suited to the method than others.

Regarding Qiagen, the Examiner maintains that the mere issue of DNA isolation is not all that is required to practice the claimed invention, as discussed *supra* and *infra*.

Anzidei et al teach that chloroplast SSR markers are particularly well-suited to the claimed process because of the high degree of sequence conservation and relative lack of recombination in the chloroplast genome, while nuclear SSR markers produce less conclusive results which do not justify their enormous monetary and labor cost (see, e.g., page 2, first full paragraph; page 6, penultimate paragraph; paragraph bridging pages 6 and 7). Anzidei et al also teach the unpredictability inherent in the use of SSR markers, regarding the lack of correlation of size with sequence (see, e.g., page 3, penultimate paragraph).

Nicese et al teach that RAPD markers are hampered by the low frequency of markers which are polymorphic or amplifiable, the high level of environmental influence thereon, the requirement for close relatedness in order to ensure accuracy, the requirement for a highly outcrossing species, the presence of markers in progeny but

absence thereof in parents, the requirement for special verification steps utilizing genotype versus primer comparisons, and the requirement of larger numbers of generations of crossing and molecular markers (see, e.g., paragraph bridging pages 201 and 202; page 202, paragraph bridging the columns; paragraph bridging pages 202 and 203; page 203, column one, first full paragraph; page 204, paragraph bridging the columns). The instant specification is completely silent regarding the applicability of RAPDs to a multitude of highly inbred tree species encompassed by the claims, the isolation of a multitude of non-exemplified RAPD markers, the performance of additional crosses and verification steps, or the creation of closely related populations. See *Genentech* cited above.

Krauss et al teach that AFLP markers require highly outcrossing species, particular steps not contemplated in the instant specification, expensive equipment and high cost; while they are hampered by the unpredictability inherent in the low frequency of polymorphism, disappearing fragments, and relative lack of accuracy inherent in bi-allelic markers (see, e.g., page 533, bottom paragraph; page 536; page 537, bottom paragraph; paragraph bridging pages 542 and 543; page 543, first three full paragraphs). Krauss et al also teach that RAPDs are hampered by limited recoverable information and low repeatability (see, e.g., page 535, first full paragraph).

Edwards et al teach that SNPs are hampered by lack of sufficient sequence variation in some plant species, the high cost of DNA sequencing which is required, the smaller amount of information presented by biallelic markers such as SNPs, the equivalence in orders of magnitude of sequencing errors and SNP occurrence rate, the

complications presented by polyploid plant species, the complications presented by introns and multigene families, and the requirement for hazardous chemicals (see, e.g., page 3, bottom two paragraphs; page 4, first and third full paragraphs; paragraph bridging pages 4 and 5; page 5, first full paragraph; page 6, middle paragraph). Edwards et al also teach the labor- and time- intensiveness of gel-based marker systems like RFLPs, RAPDs, AFLPs and microsatellites (see, e.g., page 1, top paragraph).

Applicant urges that the art rejection is improper, given the failure of the cited references to provide motivation for their combination to obtain the claimed invention. The Examiner maintains that motivation can be implicitly found within the references and within the state of the prior art, as stated previously. Furthermore, Applicant has not actually demonstrated the reduction to practice of the claimed invention as it relates to the selection of actual "elite trees". Finally, the scope of the claims is not commensurate with Applicant's single working example, contrary to the requirements of *Lindner* and *Grasselli* cited previously.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

October 13, 2004

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

